

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TOM L. CANTOR

Appeal 2008-0590
Application 10/405,974
Technology Center 3700

Decided: November 7, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 31-40,
51-59, and 63-70. Jurisdiction is under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are drawn to a device comprising an adsorption container that comprises a binding means which is specific for affixing an infecting bacterium, and methods of using the device. Claims 31-40, 51-59, and 63-70 are pending and stand rejected as follows:

Claims 31, 33, 35, 38-40, 58, and 59 under 35 U.S.C. § 102(b) as anticipated by Zimmermann et al. (U.S. Pat. No. 6,090,292, Jul. 18, 2000) (Ans.¹ 3);

Claims 32, 34, and 51-55 under 35 U.S.C. § 103(a) as obvious over Zimmermann (Ans. 4); and

Claims 36, 37, 56, 57, and 63-70 under 35 U.S.C § 103(a) as obvious over Zimmermann and McCain et al. (U.S. Pat. No. 4,737,544, Apr. 12, 1988) (Ans. 6).

Claims 31 and 63 are representative and read as follows:

31. A device for treating a patient having a severe peripheral bacterial infection, wherein the device comprises:

at least one adsorption container having an inlet means and an outlet means, where the inlet means and outlet means allow the patient's blood, in a whole or separated form, to be circulated through the adsorption container;

a first binding means associated with a solid support, wherein the first binding means is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection, and the solid support is disposed and confined within the adsorption container;

thereby allowing for the removal of at least a portion of the infecting bacterium when the patient's blood is circulated through the adsorption container.

¹ "Ans." refers to the Answer with a mail date of Jul. 16, 2007.

63. A method for treating a patient having a severe peripheral bacterial infection, the method comprising circulating the patient's blood, in whole or separated form, through an adsorption container and returning the treated blood to the patient,

wherein the adsorption container comprises an inlet means and an outlet means to allow blood to circulate through the adsorption container;

a solid support is disposed and confined within the adsorption container;

and a first binding means that is specific for affixing an infecting bacterium that is causing the severe peripheral bacterial infection is associated with the solid support;

thereby removing at least a portion of the infecting bacterium from the patient's blood when the blood is circulated through the adsorption container.

ANTICIPATION BY ZIMMERMANN

Claims 31, 33, 35, 38-40, 58, and 59 stand rejected under 35 U.S.C. § 102(b) as anticipated by Zimmermann.

Issue

The principal issue in this rejection is the proper interpretation of the claimed "binding means" which is "specific for affixing an infecting bacterium." Appellant argues that "binding means" as recited in the claims is a "means-plus-function" limitation that invokes § 112, sixth paragraph, limiting it to the materials and structures disclosed in the Specification and their equivalents (App. Br.² 5). The Examiner contends that "binding means" does not invoke § 112, sixth paragraph, and interprets it more broadly than the specific disclosure in the Specification (Ans. 8-9). Thus, we first turn to the claim interpretation issue.

² "App. Br" refers to the Appeal Brief dated Apr. 2, 2007.

The claimed “binding means” must be “specific for affixing an infecting bacterium.” That is, bacterial specificity is a characteristic of the binding means. Turning to the Specification for clarification as we do when interpreting claims (*In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)), we find materials are disclosed in it which are specific for bacteria (antibodies) and not specific for bacteria (i.e., “ConA” and “lectins”) (Spec. ¶¶ 11, 31, 32). The working examples describe the use of a “specific” antibody against *Bacillus anthracis* which is prepared by immunizing against the bacteria and then separating specific antibodies from antibodies that are not “against” the targeted bacteria (*id.* at ¶¶ 31-35). The specific antibody is able to affix or attach to the bacteria, enabling the bacteria to be removed from the patient’s blood (*id.* at ¶¶ at 2, 9). In this context, we interpret the claimed “binding means” which is “specific for affixing an infecting bacterium” to mean a material that is specific for bacteria, such as antibodies, i.e., which is “against” the bacteria (by binding and fixing it), but not against other materials.

Because it is clear that a “binding means” which is “specific for affixing an infecting bacterium” includes at least antibodies, and this determination is sufficient to reach all the prior art rejections at issue in this appeal, it is unnecessary for us to decide whether the claimed “binding means” is also a “means-plus-function” limitation that requires interpretation under § 112, sixth paragraph.

Findings of Fact

THE ZIMMERMANN PATENT

1. Zimmermann describes a device for purifying protein-containing solutions such as blood and blood plasma (Zimmermann, Abstract).

2. “This object is achieved by a device having a biocompatible support material . . . covalently coated with albumin” (Zimmermann, at col. 2, ll. 30-36).
3. The support material can be packed into a perfusable column with an inlet and outlet (Zimmermann, at col. 2, ll. 43-48; Ans. 3).
4. Albumin is known to bind “metabolic toxins such as mercaptans, free fatty acids, unconjugated bilirubin and endotoxins of gram-negative bacteria as well as many exogenous toxins, specifically medications such as nortriptyline, amitriptyline, diazepam, bromazepam, etc.” (Zimmermann, at col. 1, ll. 12-19; *see also* at col. 4, ll. 45-46).

Analysis

Anticipation requires that every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In this case, we do not agree with the Examiner that Zimmermann describes a “binding means” which is “specific for affixing an infecting bacterium” as recited in the claims. Albumin is characterized by Zimmermann as binding to metabolic toxins, endotoxins, exogenous toxins, and various medications (FF4). The Examiner has presented no evidence that it would be “specific for affixing” bacteria, but not other materials, as required by the claim language (*see supra* at p. 4). The Examiner states that Zimmermann’s device can remove gram-negative bacterial endotoxins from blood (Ans. 10), but does not explain how this property would form the basis for reasonably believing³ that albumin could bind to a bacterium, let

³ The PTO does not have the ability “to manufacture products or to obtain and compare prior art products.” *In re Best*, 562 F.2d 1252, 1255 (CCPA

alone specifically affix it as required by the claims. Accordingly, we reverse the rejection of claim 31, and dependent claims 33, 35, 38-40, 58, and 59, as anticipated by Zimmermann.

OBVIOUSNESS OVER ZIMMERMANN

Claims 32, 34, and 51-55 stand rejected under 35 U.S.C. § 103(a) as obvious over Zimmermann.

Claims 32, 34, and 51-55 depend on claim 31. As we have found that Zimmermann does not describe a “binding means . . . specific for affixing an infecting bacterium” as in claim 31, and the Examiner does not provide a reason why it would have been obvious from Zimmermann’s disclosure alone to have made such a binding means, we reverse the rejection of claims 32, 34, and 51-55 for the same reason that we concluded claim 31 is not anticipated by Zimmermann.

OBVIOUSNESS OVER ZIMMERMANN AND MCCAIN

Claims 36, 37, 56, 57, and 63-70 stand rejected under 35 U.S.C. § 103(a) as obvious over Zimmermann and McCain.

Findings of Fact

In making an obviousness determination, we must first ascertain the scope and content of the prior art. Findings of Fact with respect to the Zimmermann patent are listed above. Findings pertinent to the McCain patent are as follows:

1977). Thus, once “the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

THE MCCAIN PATENT

5. McCain describes “a biospecific polymer having immobilized reactive biologicals” which “have a high specific activity for binding complements which are pathological effectors” (McCain, at col. 3, ll. 28-31).
6. The biospecific polymer is utilized to treat diseases by removing “specific pathological effectors” from the blood (McCain, at col. 10, ll. 16-25).
7. Immunoglobulins (antibodies) are listed as an example of an immobilized reactive biological which can be utilized in McCain’s biospecific polymer to bind and remove pathological effectors (McCain, at col. 6, l. 3).
8. McCain’s working examples utilize antibodies and describe coupling them to solid supports (McCain, at col. 15, l. 9 to col. 19, l. 34).
9. McCain teaches that various disease states can be treated with its biospecific polymer (FF6) and lists “infections” among six specific disease categories (McCain, at col. 10, ll. 54-58).
10. McCain states that these disease states can be treated by removal of a specific substance, i.e., pathological effectors (McCain, at col. 10, ll. 23-24, 48-49, and 59-63).
11. Bacteria, such as streptococci, are specifically identified as an infectious agent associated with infection that can be treated with the biospecific polymer (McCain, at col. 11, ll. 16-17) and thus logically would be understood by skilled persons as an effector to be removed by McCain’s biospecific polymer.
12. McCain describes using its method with whole blood. In this method, the blood is removed from the patient, contacted with the biospecific

polymer, and then the treated blood is returned to the patient (McCain, at col. 13, l. 56 to col. 14, l. 1).

Difference between the prior art and the claimed invention

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103(a). The following findings of fact are pertinent to this determination:

13. The Examiner finds that “Zimmermann discloses the apparatus and method substantially as claimed,” but does not describe the claimed “binding means as an immunoglobulin, monoclonal, or polyclonal antibody that adsorbs a bacterium” as in the claims (Ans. 6-7).

14. However, the Examiner finds that McCain teaches “that bacterial infections . . . may be treated with biospecific polymers that may be comprised of immunoglobulins and antibodies (see column 6, lines 1-15)” (Ans. 7; FF6, 7, 11).

Reason to combine the prior art

15. Persons of ordinary skill in the art would have been prompted to utilize the specific binding means described by McCain in Zimmermann’s device for removing bacteria in order to treat bacterial infection as taught by McCain (*see* Ans. 7, 10, and 13).

Analysis

Claims 36, 37, 63, 65, and 68-70

The principal issues in this rejection are: 1) whether McCain suggests using antibodies as a binding means to remove bacteria as in claims 36 and

37; and 2) whether McCain suggests removing bacteria with a binding means as in claim 63.

McCain clearly teaches that antibodies may be used as biospecific polymers to remove pathological effectors (FF7) and lists bacteria as a pathological effector – i.e., an infectious agent – associated with infection that can be treated with its biospecific polymers (FF11). McCain does not explicitly state that the antibodies can be used as a biospecific polymer to remove bacteria, but such a disclosure is not necessary to establish prima facie obviousness of claims 36, 37, and others. An invention may not be patented if the differences between the claimed invention and the prior art would have been obvious to persons of ordinary skill in the art. 35 U.S.C. § 103(a). Thus, the standard for obviousness under Section 103 is not whether each element of the claimed invention is disclosed in the art as it is for Section 102, but whether the differences between the prior art and the claimed invention would have been obvious.

In this case, antibodies are one in a list of biologicals that can be used in McCain's method to remove pathological effectors (FF7). Antibodies are also used in the working examples (FF8). Appellant contends that the Examiner improperly utilized "hindsight" because antibodies appear in a "laundry list" of biologicals and that there is "no indication that they are separately preferred" (App. Br. 33). However, the fact that antibodies are disclosed by McCain is evidence that they were contemplated for use by McCain and expected to work. And, in fact, antibodies were utilized in the working examples (FF8). It is well settled that, "in a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred

embodiments, must be considered.” *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976). Thus, “[a]ll the disclosures in a reference must be evaluated, including nonpreferred embodiments.” *In re Mills*, 470 F.2d 649, 651 (CCPA 1972) (citations omitted).

Appellant further contends that there is no guidance that would have led persons of ordinary skill in the art to select antibodies from the list of biologicals and then to select infection as a disease state (App. Br. 33). He urges that this “combination appears to have been selected solely based on the Applicant’s disclosure, using an improper hindsight analysis” (*id.*).

This argument does not convince us that the Examiner erred. McCain has disclosed a number of different biologicals useful to remove pathological effectors from blood (FF7). Antibodies are among those listed and are specifically used in certain examples (FF8). McCain also lists six specific disease states which can be treated with these biologicals (FF9). Based on this disclosure, persons of ordinary skill in the art would have recognized that each biological, including antibodies, could be used to treat any one of the six specifically disclosed disease states, including infection, if the biological bound to the pathological effector causing the disease.

McCain describes its method very generically and as applicable to a variety of different diseases and disease states. Thus, it does not appear that McCain’s invention would be understood as restricted to the specific and preferred examples, but instead would more broadly be construed as a general teaching of the utility of biologicals for treatment of diseases. This conclusion is clearly reflected in the following statement by McCain:

Today, plasmapheresis and cytophoresis [sic] are the treatments for disease by removal of noxious substances or cells from the blood. It is currently believed that any disease treated by plasmapheresis and/or cytophoresis, where the desired result is the removal of a specific substance, can be advantageously treated with the product and process of the present invention.

(McCain, at col. 13, ll. 49-55.) Thus, persons of ordinary skill in the art would clearly have recognized that antibodies, one of the specific biologicals disclosed in McCain, could be used to treat infection, one of the six identified disease states.

Appellant also argues that “the references do not disclose selective removal of bacteria or any type of cells from blood” (App. Br. 35). However, McCain explicitly teaches that its methods are for removing pathological effectors (FF5, 10). When the disease to be treated is an infection, it would be logical that the effector of the infection – i.e., the bacterium – would be targeted for removal (FF11). McCain does not expressly state that its biospecific polymer could be used to remove bacteria from the blood, but in view of its teaching of removing pathological effectors associated with disease, including diseases caused by infectious agents, persons of ordinary skill in the art would have been prompted to have removed bacteria from blood as in claim 63. “A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007). The analysis under 35 U.S.C. § 103 therefore “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 1741.

Appellant also states that Zimmermann “teaches away from using other types of binding agents by suggesting that its *only* disclosed binding agent, albumin covalently bound by peptide bonds to a solid support, is especially suited to achieve its objectives (col. 2:36-8), while disparaging a known ‘albumin-coated adsorber’ because it was not steam hemocompatible or sterilizable (col. 2:13-17)” (App. Br. 37).

This argument is not persuasive. A solid support with antibodies is expressly taught by McCain (FF8). Based on McCain’s teaching that the pathological effector is removed from blood outside the body and then returned to the patient (FF12), either McCain’s device would be understood to have an inlet or outlet to meet all the limitations of claims 36 and 37, or it would have been obvious to have utilized a container with an inlet and outlet as taught by Zimmermann (FF3) in order to contact blood with the polymer and then return it to the patient.

For the foregoing reasons, we affirm the rejections of claims 36, 37, and 63. Claims 65 and 68-70 fall with claims 36, 37, and 63 because separate reasons for their patentability were not provided. *See* 37 CFR § 41.37(c)(1)(vii).

Claims 56 and 57

Claims 56 and 57 depend on claim 51 which recites, inter alia, that the device of claim 31 further comprises a second binding means which is “specific for affixing at least one toxin produced by an infecting bacterium that is causing the severe peripheral bacterial infection.” Claims 56 and 57 further specify that the binding means for affixing the toxin is an immunoadsorbent and antibody, respectively.

Zimmermann expressly teaches that albumin can be utilized to remove bacterial toxins (FF4). McCain also teaches that its methods can be used for toxins (McCain, at col. 11, ll. 5-7). Furthermore, McCain teaches that its therapeutic treatment method can involve “two or more biospecific polymers each having the same or different reactive biologicals or groups of biologicals” (McCain, at col. 29, l. 14 to col. 30, l. 3). McCain also uses antibodies in its method (FF7-8) which are immunoabsorbents. Thus, persons of ordinary skill in the art would have been prompted to utilize one antibody to remove bacteria and another antibody to remove a toxin associated with the bacteria in order to fully treat the bacterial infection for the reasons provided by McCain (*see* FF6).

Appellant argues that there is no specific teaching in the cited prior art that would have led to a second binding means for removing toxins (App. Br. 36-37). We do not agree. McCain specifically mentions toxins (McCain, at col. 11, ll. 5-7), albeit not bacterial. Zimmermann teaches removing bacterial endotoxins (FF4). Thus, there is express reason to have utilized a binding means specific for toxins as recited in the claims. We affirm the rejection of claims 56 and 57 as obvious over the combination of Zimmermann and McCain.

Claims 64, 66, and 67

Appellant separately addresses claims 64, 66, and 67.

Claims 64 is directed to the method of independent claim 63 in which “the blood is circulated through the adsorption container until the bacterial load has been reduced to a level such that the use of an antibiotic does not put the patient at a significant risk of induced bacteremia or septicemia.”

Claim 66 is drawn to the method of claim 63 “in which the blood is monitored for the reduction in the level of bacteria.”

Each of Zimmermann and McCain teach removing pathological effectors from the blood. It would be logical to remove as much of the effector as possible from the blood, since it would have been recognized that leaving bacteria would allow for recolonization of the host and recurrence of the disease. Such reduction in bacterial load would inherently result in reduced risk of bacteremia or septicemia as recited in claim 64.

Appellant argues the “Examiner has not shown that the prior art recognized bacterial load as a result-effective variable for a treatment related to removing bacteria from blood” (App. Br. 41). This argument is not persuasive. For the reasons discussed above, persons of skill in the art would have recognized the benefit of removing the pathological effector from the blood. An explicit teaching from the prior art is not necessary to establish prima facie obviousness. In this case, there is a sound scientific reason which would have prompted the ordinary skilled worker to achieve the claimed invention. Appellant has not provided any evidence to the contrary. Thus, we affirm the rejection of claim 64.

Since bacteria are the pathogenic agent, it would be the logical agent to monitor as in claim 66. We also affirm the rejection of claim 66.

Claim 67 is directed to the method of claim 63 in which “any antibiotic treatment of the patient is curtailed until the infecting bacterial load has been lowered to an acceptable risk level.” We agree with Appellant that Examiner has not provided any reason that would have prompted persons of ordinary skill in the art to curtail antibiotic treatment (App. Br. 42). Consequently, we reverse the rejection of claim 67.

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CONCLUSION

In summary, we reverse the anticipation and obviousness rejections of claims 31-35, 38-40, 51-55, 58, and 59 over Zimmermann. We affirm the obviousness rejection of claims 36, 37, 56, 57, 63-66, and 68-70 over Zimmermann and McCain, but reverse the rejection of claim 67 over the same references.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

cdc

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